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Excerpt from
Generic Biologics: The Next Frontier
(June 2001)

Generic Biologics: The Next Frontier

USA Specialty Pharmaceuticals

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Team

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Special Report

- Biological products are approaching the end of their market exclusivity with over $10 billion in 2000 sales coming off patent over the next five years.
- There are proposed regulations to prove equivalent biotech products in the relative near term, and additional regulatory clarity is likely to come in the months ahead.
- We believe that generic biologic products represent a significant opportunity and anticipate progress on this cutting edge of technology.

Table of Contents

Highlights and Overview

Specialty Pharmaceuticals

Generic Biologics: The Next Frontier

- Approximately 20 years ago, the first biopharmaceutical products were patented in the United States. Over the next five years, more than $10 billion worth of products will come off patent.
- Recognizing an untapped opportunity, a handful of companies are focusing on the development and commercialization of generic biopharmaceutical products. Although no regulatory infrastructure presently exists in the United States for such an undertaking, there is potential elsewhere; and it will likely exist domestically in the coming years.
- With only a select number of companies capable of competing in this sector, the potential is significant. Generally, companies taking advantage of this have a unique combination of biopharmaceutical knowledge and manufacturing expertise.
- We believe that advances in science have brought this once nebulous picture into clearer view. Furthermore, key cases on the matter offer insight into the possibility.
- We believe that a U.S. legislative initiative to create an approval pathway is simply a matter of time, and foresee generic biopharmaceutical product launches abroad and eventually in the United States.

Executive Summary

We believe that the potential for generic biopharmaceutical products is building, and that the opportunity for first movers into the field can be enormous. Through 2006, over $10 billion worth of branded biologics are scheduled to go off patent, gaining the attention of generic pharmaceutical manufacturers, Congress and federal regulators. However, because of the intrinsic differences from conventional pharmaceuticals, as well as differences in the oversight and manner in which they are regulated, generic biopharmaceutical products face a number of unresolved issues inhibiting progress toward establishing rules for the approval and marketing of such compounds.

Nonetheless, we believe that the pieces are beginning to fall into place, with many of the biotechnology industry's arguments declining in influence. First, one of BIO's primary arguments—that different cell lines cannot produce equivalent products—is ironically refuted by Biogen, one of biotech's leaders. It's drug, Avonex®, was approved for marketing, despite the fact that clinical trials were conducted with product produced from a different cell line than the one used to produce the current marketed product. Second, the *Serono v. Shalala* ruling established that the power to determine "sameness" lay with FDA and that a therapeutically equivalent biologic can be achieved. Third, FDA has proposed a potential pathway for generic biologic approval using an established procedure. Fourth, U.S. Pharmacopeia has offered to set up standards for the characterization of generic biologics, providing a highly respected, independent voice in favor of the concept. Finally, interest in Congress appears to be growing toward examining the possibility of establishing new regulations for the approval of generic biologics as part of a comprehensive reform of the overall Waxman-Hatch framework.

Accordingly, many companies, including Sicor, Teva and Ivax, have begun making preparations for the manufacture and sales of generic biologics. By being first movers into this valuable marketplace, the most aggressive companies stand to reap the greatest benefits, and may end up years ahead of the competition.

With attention increasing on the high costs of drugs in general and the extremely high costs of biotech drugs, the political climate has begun to shift toward making these drugs more affordable to the average citizen. We believe that infinite patent lives for biotech products are unfeasible in the current political environment. Additionally, generic products have been widely successful on many fronts for conventional pharmaceuticals. As such, we believe that the United States government will take the necessary steps to establish guidelines for generic biologics as part of a comprehensive Waxman-Hatch reform, or as part of an effort to add a prescription drug benefit to the Medicare program.